

The opinion in support of the decision being
entered today is not binding precedent of the Board.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

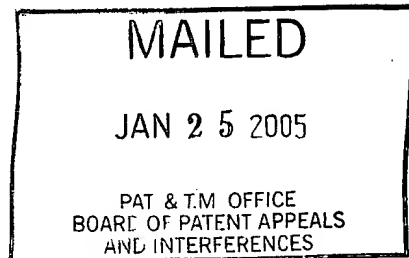
ALBERTO STAMPA, PELAYO CAMPS, GLORIA RODRIGUEZ,
JORDI BOSCH and MARIA DEL CARMEN ONRUBIA

Junior Party,

v.

WILLIAM P. JACKSON

Senior Party,



Patent Interference Nos. **105,069 and 105,212**

Before: SPIEGEL, LANE and TIERNEY, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

DECISION - PRELIMINARY MOTIONS & REHEARING

Bd. R. 125

**(Decision on Stampa Preliminary Motions 1, 2 and 3 and
Stampa Request for Rehearing)**

A Decision on Preliminary Motions (Paper No. 69)¹ was entered in this interference. In that Decision, Stampa Preliminary Motions 1-3, which requested that Jackson's involved claims be held unpatentable, were denied-in-part and deferred-in-part. Stampa has requested reconsideration of Decision on Preliminary Motions to the extent the decision denied Stampa Preliminary Motions 1-3.

A decision on priority of invention in Interferences 105,069 and 105,212 is being concurrently decided by a merits panel of the Board. As set forth in the Standing Order (Paper No. 2), a panel conducting a review of an interlocutory decision is generally the same panel that entered the interlocutory decision. (Paper No. 2, § 53). As such, the merits panel has referred consideration of the deferred parts of Stampa Preliminary Motions 1-3 as well as Stampa's request for rehearing of the denied parts of Stampa Preliminary Motions 1-3 to the same motions panel that entered the original decision (Paper No. 69, pages 43-46, 48).

I. Summary of the Decision

Stampa requests reconsideration of the Decision on Preliminary Motions (Paper No. 69). Stampa Preliminary Motions 1-3 alleged that Jackson's involved claims lacked definiteness, enablement and written description. As explained in the Decision on Preliminary Motions, the Board determined that Stampa Preliminary Motions 1-3 failed to address each of the claims alleged to be unpatentable. The Board held that Stampa Preliminary Motions 1-3 were denied with respect to claims where Stampa failed to articulate a specific, identifiable basis for

¹Paper number citations are to the 105,069 interference unless otherwise stated.

unpatentability and deferred consideration of the motions with respect to the remaining claims. Stampa's request for rehearing (Paper No. 110) alleges that the Board overlooked or misapprehended that Stampa's preliminary motions presented arguments that are applicable to all of Jackson's claims and not just those claims specifically identified in the motions. We have considered Stampa Preliminary Motions 1-3 as well as Stampa's request for rehearing and determined that Stampa has failed to demonstrate that Jackson's claims lack definiteness, written description, and/or enablement. Thus, we have considered Stampa Preliminary Motions 1-3 as they pertain to all of Jackson's claims, but deny the relief requested in the preliminary motions and in Stampa's request for reconsideration.

II. Findings of Fact

A. The Involved Jackson Claims

1. Jackson's U.S. Patent No. 6,093,827 ('827 patent) and U.S. Application No. 09/525,894 ('894 application) are involved in Interference No. 105,069. (Notice Redeclaring Interference, Paper No. 76).
2. Jackson's '894 application is involved in the 105,212 interference, but not the '827 patent. (Interference 105,212, Notice Declaring Interference, Paper No. 1).
3. Jackson's '894 application is said to be a continuation of U.S. Application Serial No. 09/383,078, which issued as Jackson's involved '827 patent.

4. Jackson's '827 patent has seventeen (17) claims and its '894 application has twenty-eight (28) claims, numbered 1-28. (*Id.*).

5. All of Jackson's '827 patent claims and '894 application claims are involved in the '069 interference. (*Id.*).

6. All of Jackson's '894 application claims, claims 1-28, are involved in the 105,212 interference. (*Id.*).

7. Claim 1 of Jackson's '894 application is identical to claim 1 of Jackson's '827 patent except that claim 1 of the '894 application employs a "consisting essentially of" transitional phrase as opposed to the "comprising" transitional phrase used in claim 1 of the '827 patent. (Jackson Clean Copy of Claims, Paper No. 7).

8. Jackson's '894 application is said to be a continuation of the application that issued as the '827 patent. Jackson's '894 application and the '827 patent appear to provide identical disclosures with respect to Jackson's invention. As such, for simplicity, references to Jackson's specification are understood to mean both the '894 and the '827 specification unless otherwise stated.

9. Additionally, Jackson's '894 and '827 claims are of the same scope except for the transitional phrase "consisting essentially of" in the '894 application and "comprising" in the '827 patent and certain improper multiple dependencies in the '894 application claims. For the sake of simplicity, a reference to one of Jackson's claims 1-17 should be understood as referring to the same claim in both the '894 application and the '827 patent unless otherwise stated.

10. Count 1 of Interference 105,069 is the sole count and is Jackson '827 claim 17. (Int. No. 105,069, Paper No. 1).

11. Count 1 of Interference 105,212 is the sole count and is Jackson '894 claim 17. (Int. No. 105,212, Paper No. 1).

B. Stampa Preliminary Motions 1-3

1. Stampa Preliminary Motion 1

12. Stampa Preliminary Motion 1 alleges that all of Jackson's involved claims are unpatentable under 35 U.S.C. §112, second paragraph for indefiniteness. (Paper No. 26, p. 2).

13. Stampa cites the following evidence as relied upon to support its allegations of indefiniteness:

1. Exhibit 2001: Declaration of Professor John E. McMurry, Ph.D.
2. Exhibit 2002: Table I.
3. Exhibit 2005: Commentary of Charles Gholz

4. Exhibit 2006: Page 5 of Jackson's Reply Brief in Opposition to the Possible Declaration of Interference Between the '827 Patent and Medichem's Reissue Application [09/380,835, filed in Int. No. 105,001]
5. Exhibit 2007: Rolabo's Motion to Reinstate Patent Infringement Counterclaim

(*Id.*).

14. Stampa Preliminary Motion 1 identifies the following Jackson claim terminology as indefinite:

1. 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene
2. Dibenzosuberone or an Aza Derivative Thereof
3. Aliphatic Ketone and Cyclic Aliphatic Ketone
4. Intermediate Diol of Formula III
5. X denotes Nitrogen or CH in Formula I
6. Jackson's Alleged Exclusion of a Tertiary Amine from its Claims.

(*Id.* at 7-15, see section headings).

- a. 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene

15. Stampa Preliminary Motion 1 states that:

The independent claims (and various dependant claims) of the '827 patent and '894 application recite a process for preparing a 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene."

(*Id.* at 7).

10. Stampa argues that since there are "virtually thousands" of potential 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene and since Jackson's specification only exemplifies preparation of two close compounds within the genus, "the claims" are unclear and indefinite. (*Id.*).

16. Stampa concludes that “[t]hus all of Jackson’s claims are indefinite and fail the requirements of Section 112, second paragraph.” (*Id.* at 8).
17. Stampa Preliminary Motion 1 does not specifically identify any particular claim by number or discuss how the various dependent claims fail to further limit the allegedly indefinite term “5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene.”
18. Jackson ‘827 patent and ‘894 application claims 17 are limited to preparations of loratadine, one of the compounds Stampa identifies as exemplified in Jackson’s specification. (*Id.*).

b. Dibenzosuberone or an Aza Derivative Thereof

19. Stampa Preliminary Motion 1 states that:
- The independent claims (and various dependant claims) of the ‘827 patent and ‘894 application recite a process for preparing any 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene with any dibenzosuberone or any aza derivative thereof.
- (*Id.*, emphasis in original).
20. The term “aza” is generally understood in the chemical arts as a prefix indicating the presence of nitrogen in a heterocyclic ring. Hawley, The Condensed Chemical Dictionary, 8th Ed., 1971, p. 86, copy attached.

21. Stampa argues that Jackson's claims are indefinite as they purport to encompass preparation of a "vastly indeterminate number of 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes" by using the "universe" of potential dibenzosuberones or aza derivatives thereof. (Paper No. 26, p. 8).

22. Stampa further argues that:

... the Jackson specification fails to teach a skilled artisan (1) that all dibenzosuberones or aza derivatives thereof behave the same way; (2) that even under the best of conditions, the McMurry Reaction is temperamental . . . or (3) how one must adjust the reaction for each of the different compounds.

(*Id.* at 8-9).

23. Stampa concludes that "[t]hus all of Jackson's claims are indefinite and fail the requirements of Section 112, second paragraph." (*Id.* at 9).

24. Stampa Preliminary Motion 1 does not specifically identify any particular claim by number or discuss how the various dependent claims fail to further limit the allegedly indefinite dibenzosuberone or an aza derivative thereof.

25. Claim 2 of Jackson's '827 patent and '894 application expressly require a dibenzosuberone where (X=CH) or an aza derivative thereof (X=N) of a defined formula I wherein R¹, R², R³ and R⁴ may be the same or different and independently denote H or a halogen.

c. Aliphatic Ketone and Cyclic Aliphatic Ketone

26. According to Stampa Preliminary Motion 1, Jackson purports to make 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes by using a universe of aliphatic ketones. (*Id.*)

27. Stampa states that claim 6 of both Jackson's '827 patent and '894 application define the ketone of claim 1 as a cyclic ketone and that this implies that claim 1 includes alicyclic ketones. (*Id.*)

28. Stampa argues that "[t]here are an incredibly vast number of cyclic and acyclic ketones" and that Jackson's specification provides no guidance as to which ketones, cyclic or acyclic, to use and there is an indefinite number of species falling within the subgenus of cyclic aliphatic ketones discussed in Jackson's specification. (*Id.* at 9-10).

29. Stampa concludes that "[t]hus the Jackson claims are indefinite and fail the requirements of Section 112, second paragraph." (*Id.* at 11).

30. Claims 7 through 9 of Jackson's '827 patent and '894 application limit the aliphatic ketone to a cyclic subgenus of optionally N-substituted piperidones.

31. Stampa Preliminary Motion 1 does not specifically identify any particular claim beyond '894 and '827 claims 1 and 6 by number or discuss how the various dependent claims fail to further limit the allegedly indefinite aliphatic ketone or cyclic aliphatic ketone.

d. Intermediate Diol of Formula III

32. Stampa Preliminary Motion 1 identifies claim 12 in Jackson's '827 patent and '894 application as requiring the preparation of an "intermediate diol" of a particular formula III. (*Id.*).

33. Stampa contends that the term "intermediate diol" is unclear and indefinite as the Jackson specification does not: 1) "support the vast number of intermediate diols purportedly encompassed by the Jackson claims;" or 2) "teach a skilled artisan that all of the possible permutations of the intermediate diol of Formula III (and there are very many) behave the same way, or that even under the best of conditions, the McMurry Reaction is temperamental." (*Id.*).

34. Stampa concludes that "[t]hus, the Jackson claims are indefinite and fail the requirements of Section 112, second paragraph." (*Id.* at 12).

35. Stampa Preliminary Motion 1 does not specifically identify any particular claim beyond '894 and '827 claim 12 by number. Stampa fails to identify how any claim other than '894 and '827 claim 12, requires an intermediate diol (e.g, Stampa has failed to establish that an

intermediate diol is necessarily and inherently produced during the recited reaction) or is rendered indefinite by the use of such term in claim 12.

e. X Denotes N or CH in Formula I

36. Stampa Preliminary Motion 1 identifies Jackson '894 and '827 claim 2 as limiting the "dibenzosuberone or aza derivative" of claim 1 to a particular formula I where X is N or CH. (*Id.*).

37. Stampa argues that Jackson's specification does not adequately support the recitation of X being CH and does not support the "universe" of aza derivatives. (*Id.*).

38. Stampa concludes that "[t]hus, the Jackson claims are indefinite and fail the requirements of Section 112, second paragraph." (*Id.* at 12).

39. Stampa Preliminary Motion 1 does not specifically identify any particular claim beyond '894 and '827 claim 2 by number. Stampa fails to identify how any Jackson claim, other than '894 and '827 claim 2, require X as N or CH or is rendered indefinite by the use of "X denotes nitrogen or CH" in formula (I) of Jackson claim 2.

f. Jackson's Alleged Exclusion of a Tertiary Amine

40. Stampa contends that Jackson's claims are not directed to the subject matter Jackson regards as his invention. In particular, Jackson is said to have sought to construe its claims as excluding a tertiary amine during the course of a judicial interference in the United States District Court for the Southern District of New York, *Medichem, S.A., v. Rolabo, S.L.*, 01 Civ. 3087. (*Id.* at 14).

41. Stampa further contends that Jackson's specification does not teach that the use of a tertiary amine is deleterious and, therefore, a skilled artisan would not know whether Jackson's "consisting essentially of" claim language excluded the use of tertiary amines. (Paper No. 26, pages 14-15).

42. The issue of whether Jackson's '827 and '894 claims exclude tertiary amines is rendered moot in light of the Decision on Preliminary Motions (Paper No. 69), which construed Jackson's involved claims as open to the inclusion of a tertiary amine. (See, e.g., Notice Declaring Interference, Paper No. 1, p. 10 and Paper No. 69 at 32-36).

2. Stampa Preliminary Motion 2 (Paper No. 27)

43. Stampa Preliminary Motion 2 alleges that all of Jackson's involved claims are unpatentable under 35 U.S.C. §112, first paragraph for lack of enablement. (Paper No. 27, p. 2).

44. Stampa cites the following evidence as relied upon to support its allegations of indefiniteness:

1. Exhibit 2001: Declaration of Professor John E. McMurry, Ph.D.
2. Exhibit 2003: Table I.
3. Exhibit 2005: Commentary of Charles Gholz
4. Exhibit 2006: Page 5 of Jackson's Reply Brief in Opposition to the Possible Declaration of Interference Between the '827 Patent and Medichem's Reissue Application [09/380,835, filed in Int. No. 105,001]
5. Exhibit 2007: Rolabo's Motion to Reinstate Patent Infringement Counterclaim

(*Id.*).

45. Stampa Preliminary Motion 2 states that Jackson's claims lack enablement arising from the use of the following claim terms:

1. 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene
2. Dibenzosuberone or an Aza Derivative Thereof
3. Aliphatic Ketone and Cyclic Aliphatic Ketone
4. Intermediate Diol of Formula III
5. X denotes Nitrogen or CH in Formula I

Stampa also states that Jackson fails to provide an enabling disclosure for Jackson's alleged exclusion of a tertiary amine from its claims. (*Id.* at 7-17, see section headings).

46. The chart below identifies how the body of Stampa Preliminary Motion 2 cites certain Jackson claims as containing the disputed claim terminology and contrasts this identification against Stampa's general conclusion that all of Jackson's claims are rendered unpatentable as lacking enablement due to the use of the disputed terminology.

| Disputed Jackson Claim Term | Claims Explicitly Identified by Stampa as Lacking Enablement Due to Use of Disputed Terminology | Stampa's Conclusion Regarding Jackson's Use of Disputed Terminology |
|--|---|---|
| 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene | "The independent claims [of the '827 patent ² and the '894 application ³] are extremely overbroad." (<i>Id.</i> at 7) | "Thus, it is respectfully submitted, that the Jackson claims are not enabled." (<i>Id.</i> at 10). |
| Dibenzosuberone or an Aza Derivative Thereof | "The independent claims of the '827 patent and the '894 application are purportedly directed to a process for preparing <u>any</u> 5,6-dihydro-11H-dibenzo [a,d]cyclohept-11-ene with <u>any</u> dibenzosuberone or <u>any</u> derivative thereof." (<i>Id.</i> at 10-11). | "Therefore, the Jackson claims are invalid as lacking enablement." (<i>Id.</i> at 12). |
| Aliphatic Ketone and Cyclic Aliphatic Ketone | "Jackson's claims are purportedly directed to a process for making the <u>universe</u> of 5,6-dihydro-11H-dibenzo [a,d]cyclohept-11-enes utilizing the <u>universe</u> of aliphatic ketones. Aliphatic ketone can be cyclic or acyclic. (Cite omitted). And with the assertion in claim 6 of both the '827 patent and the '894 application that the aliphatic ketone is <u>cyclic</u> , Jackson implies that the aliphatic ketone genus claimed in claim 1 includes <u>acyclic</u> ketones." (<i>Id.</i> at 12). | "Thus, the Jackson claims are invalid as lacking enablement." (<i>Id.</i> at 14). |
| Intermediate Diol of Formula III | Stampa identifies Jackson '827 and '894 claim 12 as reciting a process involving an intermediate diol of formula III. (<i>Id.</i> at 14). | "Thus, the Jackson claims are invalid as lacking enablement." (<i>Id.</i> at 15). |

²Claim 1 is the only independent claim in the '827 patent.

³The independent claims in the '894 application are claims 1, 18, 21, 23, 24 and 26.

| | | |
|---|--|--|
| X denotes Nitrogen or CH in Formula I | Stampa identifies Jackson claim 2 of both the '827 patent and the '894 application as requiring a dibenzosuberone of formula I where X is defined as nitrogen or CH. (<i>Id.</i> at 15). | "Thus, the Jackson claims are invalid as lacking enablement." (<i>Id.</i> at 16). |
| Jackson's Alleged Exclusion of a Tertiary Amine from its Claims | Stampa argues that all claims of Stampa's '827 patent were construed as excluding a tertiary amine and that Jackson has taken the position that the '894 applications "consisting essentially of" language excludes a tertiary amine. (<i>Id.</i> at 16). | Stampa argues that Jackson's construction of the term is inconsistent with its specification and thus Jackson's involved claims are invalid because undue experimentation would be required to practice the claimed invention. (<i>Id.</i> at 16-17). |

3. Stampa Preliminary Motion 3 (Paper No. 28)

47. Stampa Preliminary Motion 3 alleges that all of Jackson's involved claims are unpatentable under 35 U.S.C. §112, first paragraph for lack of written description. (Paper No. 28, p. 2).

48. Stampa cites the following evidence as relied upon to support its allegations of indefiniteness:

1. Exhibit 2001: Declaration of Professor John E. McMurry, Ph.D.
2. Exhibit 2004: Table I.
3. Exhibit 2006: Page 5 of Jackson's Reply Brief in Opposition to the Possible Declaration of Interference Between the '827 Patent and Medichem's Reissue Application [09/380,835, filed in Int. No. 105,001]
4. Exhibit 2007: Rolabo's Motion to Reinstate Patent Infringement Counterclaim

(*Id.*).

49. Stampa Preliminary Motion 3 alleges that Jackson's specification fails to provide adequate written descriptive support for the following claim terms:

1. 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene
2. Dibenzosuberone or an Aza Derivative Thereof
3. Aliphatic Ketone and Cyclic Aliphatic Ketone
4. Intermediate Diol of Formula III
5. X denotes Nitrogen or CH in Formula I

Stampa also states that Jackson fails to provide an adequate written description for Jackson's alleged exclusion of a tertiary amine from its claims. (*Id.* at 7-16, see section headings).

50. The chart below identifies how the body of Stampa Preliminary Motion 3 cites certain Jackson claims as containing the disputed claim terminology and contrasts this identification against Stampa's general conclusion that all of Jackson's claims are rendered unpatentable as lacking written descriptive support due to the use of the disputed terminology.

| Disputed Jackson Claim Term | Claims Explicitly Identified by Stampa as Lacking Enablement Due to Use of Disputed Terminology | Stampa's Conclusion Regarding Jackson's Use of Disputed Terminology |
|--|---|--|
| 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene | "The independent claims (and various dependent claims) of the '827 patent and the '894 application recite a process for preparing a 5,6-dihydro-11H-dibenzo [a,d]cyclohept-11-ene." Stampa states that "there are virtually thousands of potential compounds within the genus (Citation omitted). (<i>Id.</i> at 7). | "Thus, the Jackson claims are invalid as failing the written description requirement of Section 112, first paragraph." (<i>Id.</i> at 7). |

| | | |
|--|--|---|
| Dibenzosuberone or an Aza Derivative Thereof | “The independent claims (and various dependent claims) of the ‘827 patent and the ‘894 application recite a process for preparing <u>any</u> 5,6-dihydro-11H-dibenzo [a,d]cyclohept-11-ene with <u>any</u> dibenzosuberone or <u>any</u> aza derivative thereof.” (<i>Id.</i>) | “Thus, the Jackson claims are invalid as failing the written description requirement of Section 112, first paragraph.” (<i>Id.</i> at 8). |
| Aliphatic Ketone and Cyclic Aliphatic Ketone | “In preparing the <u>universe</u> of 5,6-dihydro-11H-dibenzo [a,d]cyclohept-11-enes, Jackson’s claims purport to do so using the <u>universe</u> of aliphatic ketones. Aliphatic ketone can be cyclic or acyclic. (Cite omitted). And with the assertion in claim 6 of both the ‘827 patent and the ‘894 application that the aliphatic ketone is <u>cyclic</u> , Jackson implies that the aliphatic ketone genus claimed in claim 1 includes <u>acyclic</u> ketones.” (<i>Id.</i> at 8). | “Thus, the Jackson claims are invalid as failing the written description requirement of Section 112, first paragraph.” (<i>Id.</i> at 13). |
| Intermediate Diol of Formula III | Stampa identifies Jackson ‘827 and ‘894 claim 12 as reciting a process involving an intermediate diol of formula III. (<i>Id.</i> at 13). | “Thus, the Jackson claims are invalid as failing the written description requirement of Section 112, first paragraph.” (<i>Id.</i> at 13). |
| X denotes Nitrogen or CH in Formula I | Stampa identifies Jackson claim 2 of both the ‘827 patent and the ‘894 application as requiring a dibenzosuberone of formula I where X is defined as nitrogen or CH. (<i>Id.</i> at 14). | “Thus, the Jackson claims are invalid as failing the written description requirement of Section 112, first paragraph.” (<i>Id.</i> at 15). |

| | | |
|---|---|--|
| Jackson's Alleged Exclusion of a Tertiary Amine from its Claims | Stampa argues that all claims of Stampa's '827 patent were construed as excluding a tertiary amine and that Jackson has taken the position that the '894 applications "consisting essentially of" language excludes a tertiary amine. (<i>Id</i> at 15). | Stampa argues that Jackson's construction of the term is inconsistent with its specification and thus Jackson's involved claims are invalid because undue experimentation would be required to practice the claimed invention. (<i>Id.</i> at 15-16). |
|---|---|--|

C. Decision on Motions (Paper No. 69).

51. The Decision on Preliminary Motions states in relevant part that:

Stampa requests that all of Jackson's claims ('827 patent claims 1-17 and '894 application claims 1-28) be held unpatentable as the claims are of such breadth that they:

- 1) lack clarity under 35 U.S.C. §112, second paragraph (Stampa Preliminary Motion 1, Paper No. 26, p. 1);
- 2) lack an enabling disclosure (Stampa Preliminary Motion 2, Paper No. 27, p.1); and
- 3) lack sufficient written description (Stampa Preliminary Motion 3, Paper No. 28, p. 1).

Stampa's request is in itself overly broad. Stampa's preliminary motions fail to address each of the claims for which they request a judgment of unpatentability. For example, Stampa Preliminary Motions 1, 2 and 3 identify claims 1, 2, 6 and 12 of the '827 patent and claims 1, 2, 6, 12, 18, 21, 23, 24 and 26 of the '894 application as being of such breadth that they are indefinite and lack sufficient written description to convey that the invention was possessed by Jackson or that one could make and use the "universe" of claimed processes.

We note that Stampa fails to specifically identify the particular basis or sufficient evidence that would support a finding that Jackson patent claims 3-5, 7-11 and 13-17, and application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28 are overly broad with respect to Jackson's specification. (Jackson Opposition 1, Paper No. 41, p. 5; Jackson Opposition 2, Paper No. 42, pages 5-6; Jackson Opposition 3, Paper No. 43, p. 6). Hence, as to Jackson patent claims 3-5, 7-11 and 13-17, and

application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28, Stampa Preliminary Motions 1, 2 and 3 are denied.

(Paper No. 69, pages 43-44).

D. Stampa Brief in Support of Reconsideration of Stampa Motions 1, 2 & 3

52. Stampa's request for reconsideration identifies the three following points that the Board allegedly misapprehends or overlooks:

- i. Stampa Preliminary Motions 1-3 asserted arguments based upon claim terms that affect all of Jackson's '827 and '894 claims by virtue of explicit recitation or dependence.
- ii. The unpatentability of Jackson's claims is not limited to a discreet subset of claims as identified in the Decision.
- iii. A decision that all of Jackson's claims are unpatentable leads to a termination of the interference.

(Paper No. 110, p. 1).

53. Additionally, Stampa's request for reconsideration argues, apparently for the first time, that a decision that all of Jackson's claims, including the Counts, are unpatentable, leads to a termination of the interference. (*Id.*). This issue is moot in light of our decision denying Stampa Preliminary Motions 1-3, which request the unpatentability of Jackson's claims, including the Counts, i.e., Jackson '827 claim 17 and '894 claim 17..

54. Stampa's request for reconsideration provides the following table that sets forth a summary of the disputed Jackson claim terminology and those Jackson claims that Stampa alleges are unpatentable stemming from the use of the disputed language.

| Complained of Jackson Claim Recitation | Affected Jackson Patent Claim(s) | Affected Jackson Application Claim(s) |
|--|----------------------------------|---------------------------------------|
| 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene | 1-16 | 1-16, 18-28 |
| Dibenzosuberone or an Aza Derivative Thereof | 1, 6-17 | 1, 6-28 |
| Aliphatic Ketone | 1-5, 10-17 | 1-5, 10-28 |
| Cyclic Aliphatic Ketone | 6-9 | 6-9 |
| Intermediate Diol | 12 | 12 |
| X denotes Nitrogen or CH | 2-4 | 2-4 |

(Paper No. 110, p. 10).

55. Stampa's Brief in Support of Reconsideration does not state where Stampa Preliminary Motions 1-3 identified the claim groupings set forth in the above table.

1. 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene

56. Stampa's Brief in Support of Reconsideration states that:

The recitations of Jackson patent claims 2-16 and Jackson application claims 2-16 and 18-28 do not remedy the deficiencies imparted by the term, "5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene." None of Jackson patent claims 2-16 and Jackson application claims 2-16 and 18-28 directly limit the term "5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene" or otherwise renders the term more definite, enabled or described.

(Paper No. 110, p. 11).

57. Stampa's Brief in Support of Reconsideration does not identify specifically where Stampa Preliminary Motions 1-3 argued that the limitations contained in Jackson's involved dependent

claims do not render the term 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene more definite, enabled or described, i.e., where the argument was allegedly misapprehended or overlooked.

58. Stampa's Brief in Support of Reconsideration does not state what evidence specifically supports its position that the limitations contained in Jackson's involved dependent claims do not render the term 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene more definite, enabled or described, i.e., where the argument was allegedly misapprehended or overlooked.

2. Dibenzosuberone or an Aza Derivative Thereof

59. Stampa's Brief in Support of Reconsideration states that:

The recitations of Jackson patent claims 6-17 and Jackson application claims 6-28 do not remedy the deficiencies imparted by the term, "dibenzosuberone or an aza derivative thereof." None of Jackson patent claims 6-17 or [sic, Jackson's application claims] 6-28 directly limits the term "dibenzosuberone or an aza derivative thereof" or otherwise renders the term more definite, enabled or described.

(Paper No. 110, p. 11).

60. Stampa's Brief in Support of Reconsideration does not identify specifically where Stampa Preliminary Motions 1-3 argued that the limitations contained in Jackson's involved dependent claims do not render the term "dibenzosuberone or an aza derivative thereof" more definite, enabled or described, i.e., where the argument was allegedly misapprehended or overlooked.

61. Stampa's Brief in Support of Reconsideration does not state what evidence specifically supports its position that the limitations contained in Jackson's involved dependent claims fail to render the term "dibenzosuberone or an aza derivative thereof" more definite, enabled or described, i.e., where the argument was allegedly misapprehended or overlooked.

3. Aliphatic Ketone and Cyclic Aliphatic Ketone

62. Stampa's Brief in Support of Reconsideration states that:

The recitations of Jackson patent claims 1-5 and 10-17 and Jackson application claims 1-5 and 10-28 do not remedy the deficiencies of the term "aliphatic ketone." None of Jackson patent claims 1-5 and 10-17 and Jackson application claims 1-5 and 10-28 directly limits the term "aliphatic ketone" or otherwise renders the term more definite, enabled or described. Indeed, claims 6-9 that involve the term "cyclic aliphatic ketone," as discussed in Stampa Preliminary Motions 1-3, illustrate that the terms "aliphatic ketone" and "cyclic aliphatic ketone" fail to meet the requirements of 35 USC §112, i.e., even when dependent claims attempt to limit a complained of Jackson claim recitation, the dependent claim recitation only highlights the deficiencies of the Jackson claim terms.

(Paper No. 110, p. 11-12).

63. Stampa's Brief in Support of Reconsideration does not identify specifically where Stampa Preliminary Motions 1-3 argued that the limitations contained in Jackson's involved dependent claims fail to render the terms "aliphatic ketone" and "cyclic aliphatic ketone" more definite, enabled or described, i.e., where the argument was allegedly misapprehended or overlooked.

64. Stampa's Brief in Support of Reconsideration does not state what evidence specifically supports its position that the limitations contained in Jackson's involved dependent claims fail to

render the terms “aliphatic ketone” and “cyclic aliphatic ketone” more definite, enabled or described, i.e., where the argument was allegedly misapprehended or overlooked.

4. Process of Making Loratadine

65. Stampa’s Brief in Support of Reconsideration, in a section labeled “(1) The Counts are Unpatenable,” states that:

Jackson patent claim 17 and Jackson application claim 17 that attempt to limit the Jackson claim term, “5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene” to “Loratadine” nonetheless fail to particularly limit the “dibenzosuberone or an aza derivative thereof” and “aliphatic ketone” reactants. Indeed, Jackson patent and Jackson application claim 17 do not provide that Loratadine is the direct product of the reaction, in the presence of low-valent titanium generated by zinc, of a “dibenzosuberone or an aza derivative thereof” and “aliphatic ketone.” And therefore, the recitation of Jackson patent and application claim 17 fails to directly limits [sic] the terms “dibenzosuberone or an aza derivative thereof” and “aliphatic ketone” or otherwise render these terms more definite, enabled or described. Thus, the recitations of Jackson patent and application claim 17 do not save these claims from failing under Section 112.

(Paper No. 110, p. 12).

66. Stampa’s Brief in Support of Reconsideration fails to identify where Stampa Preliminary Motions 1-3 argued that Jackson patent and application claim 17 were indefinite, lacked enablement or lacked written description or that the Counts were unpatentable. Further, Stampa’s brief does not state what evidence specifically supports this allegation. In other words, Stampa fails to point out where in the original record this argument and supporting evidence was overlooked or misapprehended.

E. Evidence Relied Upon in Support of Stampa Preliminary Motions 1-3

1. Declaration of Professor John E. McMurry, Ph.D. (SX 2001)

67. Dr. McMurry testifies that:

From my reading of the '827 patent and '894 application, the Jackson claims, except as to possibly claim 17, are not clear, nor precise, are not adequately described in the specification of the '827 patent and '894 application, and require undue experimentation to practice.

(SX 2001, ¶ 5).

68. Dr. McMurry's declaration states:

The independent claims of the '827 patent and '894 application recite a process for preparing *any* 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene comprising (or consisting essentially of) reacting *any* dibenzosuberone or *any* aza derivative thereof with *any* aliphatic ketone in the presence of low valent titanium. Further, the dependent claims of both the Jackson patent and application recite X being N or CH (claim 2), the aliphatic ketone being cyclic (claim 6) and *any* intermediate diol of the formula III being produced (claim 12).

(SX 2001, ¶ 6, emphasis in original).

69. Dr. McMurry testifies that one skilled in the art would be at an "extreme" disadvantage as to what is needed to practice Jackson's claims and that precision and care must be employed when using the "somewhat temperamental" McMurry reaction. Specifically, Dr. McMurry testifies that:

A skilled artisan reading these claims [Jackson's independent claims as well as dependent claims 2, 6 and 12], however, would be hard-pressed to know, for example, which 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene could be prepared using the process of the Jackson claims; which dibenzosuberone or which aza derivative thereof could be used; which aliphatic ketone from the hundreds

available to a skilled artisan would react with the dibenzosuberone or the aza derivative thereof to make 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes; and which intermediate diol species from the genus of formula III could be produced. A skilled artisan, therefore, would be at an extreme disadvantage as to what is needed to practice that which Jackson claims. This is especially so as the Jackson claims utilize the McMurry reaction. The McMurry Reaction is somewhat temperamental and requires a skilled artisan to exercise care and precision even under routine experimental conditions.

(SX 2001, ¶ 7).

70. Dr. McMurry generally testifies that the terms: 1) 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes, 2) dibenzosuberone or aza derivative thereof; 3) aliphatic ketones, including cyclic and acyclic aliphatic ketones, define a “universe” of compounds. (SX 2001, ¶¶ 8-11). According to Dr. McMurry, “[t]he specification provides no guidance, support or a teaching that would lead a skilled artisan to practice the entire breadth of that which Jackson claims without excessive and burdensome experimentation.” (SX 2001, ¶ 8).

2. Stampa’s “Table I” (SX 2002, SX 2003 & SX 2004)

71. Stampa attached an appendix labeled “Table I” to each of Stampa Preliminary Motions 1, 2 and 3.

72. Each of Stampa’s “Table I” identifies Jackson ‘827 patent claims 1, 2, 6, 12 and ‘894 application claims 1, 6, 12, 18, 21, 23, 24 and 26.

73. Stampa's Table I's, (SX 2002, SX 2003 and SX 2004), are three column tables with: 1) Column 1 reciting Jackson's claim language; 2) Column 2 identifying the disputed text contained within the claims; and 3) Column 3 identifying Stampa's allegation as to why the Jackson claims are unpatentable and providing a cite, where appropriate, to Dr. McMurry's declaration (SX 2001) and to Stampa's statements of fact.

3. Letter from Charles L. Gholz, Dated April 4, 2003 (SX 2005)

74. Stampa has submitted into the record a copy of a letter apparently sent from a Mr. Charles L. Gholz to the attorneys representing Jackson and Stampa in this interference. The letter states that Mr. Gholz is enclosing a revised version of a draft document.

75. Attached to the letter is a document that discusses the declaration of this interference.

76. In footnote 10 on page 4 of the attached document, the following statement is made:

Judge Tierney's own analysis of the interfering claims erroneously states that "Both processes involve reacting a dibenzob-suberone [sic] with an aliphatic ketone, such as ethyl 4-oxopiperidine-1-carboxylate." 65 USPQ2d at 1946. However, the latter compound is a heterocyclic ketone, not an aliphatic ketone. See In re Cavallito, 306 F.2d 505, 510, 134 USPQ 370, 374 (CCPA 1962), for definitions of "aliphatic." Thus, Stampa's reactant ketone is not simply a typical member of Jackson's class of "aliphatic ketones."

(SX 2005, attached document, p. 4, n. 10).

77. Jackson's '827 patent specification states that "[p]referably the aliphatic ketone is cyclic and particularly preferably is an optionally N-substituted piperidone compound." (JX 1001, col. 2, lines 49-51).

78. Dr. McMurry testifies that aliphatic ketones may be cyclic. (SX 2001, ¶ 9).

79. At least one organic chemistry textbook has defined aliphatic as encompassing cyclic compounds. Specifically, Solomons, Organic Chemistry, teaches that "[a]n aliphatic compound is a compound such as an alkane, alkene, alkyne, cycloalkane, cycloalkene, or any of their derivatives." Solomons, Organic Chemistry, 3rd Ed., 1984, p. 468, copy attached.

4. Page 5 of Jackson's Reply Brief in Opposition to the Possible Declaration of Interference Between the '827 Patent and Medichem's Reissue Application (SX 2006)

80. Stampa has submitted as an exhibit a page from a Jackson reply brief submitted in Interference 105,001. The exhibit allegedly demonstrates that Jackson has taken the position that the "consisting essentially of" transition, as it is used in Jackson's application claims, "excludes the use of a tertiary amine from the claimed process." (SX 2006).

5. Rolabo's Motion to Reinstate Patent Infringement Counterclaim
(SX 2007)

81. Stampa has submitted as an exhibit a Rolabo (Jackson) motion filed in district court. The motion states:

On May 7, 2002, after a court trial, this Court ruled in Rolabo's favor holding that Rolabo's patented process for making loratadine did not interfere with Medichem's. The Court based its holding on the fact that Medichem's narrowly claimed invention for making loratadine required the use of a tertiary amine, while Rolabo's broadly claimed invention for making loratadine did not require the use of a tertiary amine.

(SX 2007, p. 2, alleged fact 7).

III. Opinion

There are three remaining preliminary motions in this interference. Stampa Preliminary Motion 1 requests that Jackson's involved claims be found unpatentable for lack of definiteness. Stampa Preliminary Motion 2 requests that Jackson's involved claims be found unpatentable for lack of enablement and Stampa Preliminary Motion 3 requests that Jackson's involved claims be found unpatentable for lack of written description. As explained above, the Decision on Preliminary Motions denied Stampa Preliminary Motions 1-3 as to those claims that were not specifically identified and argued and deferred resolution of the merits of the motions as to the remaining claims. Stampa requests reconsideration of the Decision on Preliminary Motions to the extent it denied Stampa Preliminary Motions 1-3.

A moving party bears the burden of proof by a preponderance of the evidence to show that it is entitled to the relief requested. 37 C.F.R. §1.633(a).⁴ The burden of showing something by a preponderance of the evidence simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Products of California, Inc. v. Construction Laborers Pension Trust for Southern California*, 508 U.S. 602, 622, 113 S.Ct. 2264, 2279 (1993).

A. Analysis of Stampa Preliminary Motions 1, 2 & 3

1. Case Law on Definiteness, Written Description and Enablement

a. Definiteness, 35 U.S.C. §112, Second Paragraph

A claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention. *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1342, 65 USPQ2d 1385, 1406 (Fed. Cir. 2003). Specifically, if the scope of the invention sought to be patented cannot be determined from the language of the claims, the specification or the teachings of the prior art with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. § 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 541, 179 USPQ 421, 423 (CCPA 1973). Thus, the question of definiteness is not

⁴See, new rule 37 C.F.R. §41.121(b). Further, the default evidentiary standard in civil proceedings is the preponderance of the evidence standard. *Price v. Symsek*, 988 F.2d 1187, 1193, 26 USPQ2d 1031, 1035 (Fed. Cir. 1993).

simply a matter of determining that a claim is written broadly. *In re Gardner*, 427 F.2d 786, 788, 166 USPQ 138, 140 (1970) (“Breadth is not indefiniteness.”).

b. Enablement, 35 U.S.C. §112, First Paragraph

To comply with the enablement requirements of 35 USC §112, first paragraph, a specification must adequately teach how to make and how to use a claimed invention throughout its scope, without undue experimentation. *Plant Genetic Systems N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003), *Enzo Biochem Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir. 1999); *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The scope of enablement is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation. *National Recovery Technologies, Inc. v. Magnetic Separation Systems, Inc.*, 166 F.3d 1190, 1196, 49 USPQ2d 1671, 1676 (Fed. Cir. 1999).

There are a variety of factors which may be considered in determining whether a disclosure would require undue experimentation. These factors include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See, *Enzo*, 188 F.3d at 1371, 52 USPQ2d at 1135-1136 (Fed. Cir. 1999); *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). In analyzing these

factors, we are mindful that a patent specification need not teach, and preferably omits, what is well known in the art. *Spectra-Physics Inc. v. Coherent Inc.*, 827 F.2d 1524, 1534, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). “The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation ‘must not be unduly extensive.’” *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) (quoting *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)).

c. Written Description, 35 U.S.C. §112, First Paragraph

While the specifics of the cases concerning adequate written description vary, the cases agree that the inquiry is *factual* and must be assessed on a *case-by-case* basis. Moreover, because of the fact-sensitive nature of the written description inquiry, the Federal Circuit has advised against misapplication of precedent in this area. See, *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 1000, 54 USPQ2d 1227, 1235 (Fed. Cir. 2000); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); and, *In re Driscoll*, 562 F.2d 1245, 1250, 195 USPQ 434, 438 (CCPA 1977).

The purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by the inventor. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991). The inventor can demonstrate possession by such descriptive means as words,

structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. The inventor, however, needs to show that the inventor was "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.

Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571-72, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The disclosure as originally filed does not have to provide *ipsis verbis* support for the claimed subject matter at issue. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996). Rather, if the written description does not use precisely the same terms used in a claim, the question then is whether the specification directs or guides one skilled in the art to the subject matter claimed such that the specification reasonably conveys to those skilled in the art that the inventor invented what is claimed. *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d at 1570, 39 USPQ2d at 1904 (Fed. Cir. 1996); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

2. Jackson's Disputed Claim Terminology

Stampa Preliminary Motion 1 alleges that Jackson's claims employ terminology that lacks definiteness. The claim language identified as indefinite is also alleged by Stampa to lack enablement (Stampa Preliminary Motion 2) and written description (Stampa Preliminary Motion 3). Our analysis of Jackson's disputed claim terminology is provided below.

a. 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene

i. Indefiniteness

Generally, Stampa alleges that the term “5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene” is indefinite as it is used in Jackson’s claims. According to Stampa, the term “5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene” is indefinite as “there are virtually thousands of potential compounds within this genus. (Paper No. 26, p. 7). Stampa further argues that Jackson’s specification provides a teaching of only two compounds from this genus and thus fails to provide “a skilled artisan with the scope of what Jackson intends to claim.” (*Id.* at 8). Stampa relies upon the first declaration of Dr. McMurry (SX 2001) to support its position.

Stampa fails to demonstrate that the term “5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene” fails to reasonably apprise those skilled in the art of the scope of the invention. Stampa fails to sufficiently identify where Dr. McMurry’s testimony or other supporting evidence demonstrates that one skilled in the art would not understand whether or not a particular compound was a 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene as called for in Jackson’s claims. At best, Dr. McMurry testifies that:

A skilled artisan reading these claims, however, would be hard-pressed to know, for example, which 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene could be prepared using the process of the Jackson claims . . .”

(SX 2001, ¶ 7, emphasis added). Reading Dr. McMurry’s testimony it appears that one skilled in the art would recognize 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene as a defined genus of recognizable compounds.

Stampa's indefiniteness argument for the term "5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene" essentially boils down to a question of whether or not a genus of thousands of potential compounds is per se indefinite. As stated above, breadth is not indefiniteness. *In re Gardner*, supra.

ii. Enablement

Regarding Jackson's enablement for the claimed process of preparing a 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene, Stampa states:

In other words, despite Jackson's claims encompassing virtually thousands of dibenzosuberones or aza derivatives thereof, virtually thousands of aliphatic ketones, and virtually thousands of resultant compounds, the Jackson specification exemplifies only **two** cycloheptenes. Jackson, therefore, does not disclose enough to enable his invention.

(Paper No. 27, p. 9). Stampa also argues that:

Applying the Wands factors, it is evident that, inter alia, the nature of the Jackson's claims is unclear; the level of one of ordinary skill is high; the level of unpredictability in the art is low; the amount of direction provided by the inventor is lacking; and the existence of working examples is directed to loratadine, simply not enough to enable the claims according to the Federal Circuit. Further, and importantly, the quantity of experimentation needed to make or use the invention based on the content of the disclosure is impermissibly great. The necessity of undue experimentation required to practice Jackson's claims is a clear failure of the enablement requirement.

(*Id.* at 10).

Stampa relies upon the first declaration of Dr. McMurry to support its arguments regarding the enablement of Jackson's claims. Dr. McMurry testifies that:

A skilled artisan reading these claims [Jackson's independent claims as well as dependent claims 2, 6 and 12] however, would be hard-pressed to know, for

example, which 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene could be prepared using the process of the Jackson claims; which dibenzosuberone or which aza derivative thereof could be used; which aliphatic ketone from the hundreds available to a skilled artisan would react with the dibenzosuberone or the aza derivative thereof to make 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes; and which intermediate diol species from the genus of formula III could be produced. A skilled artisan, therefore, would be at an extreme disadvantage as to what is needed to practice that which Jackson claims. This is especially so as the Jackson claims utilize the McMurry reaction. The McMurry Reaction is somewhat temperamental and requires a skilled artisan to exercise care and precision even under routine experimental conditions.

(SX 2001, ¶ 7).

Dr. McMurry may have testified that the McMurry reaction is somewhat temperamental, but places the caveat that this requires a skilled artisan to exercise “care and precision” when conducting the reaction. Further, although Dr. McMurry states that undue experimentation would be required to conduct Jackson’s claimed process of preparing a 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene compound, Dr. McMurry does not provide a credible basis beyond the alleged minimal disclosure of working examples and the breadth of the claims to support the proposition that undue experimentation would be necessary.

Nothing in our rules or in our jurisprudence requires us to credit the unsupported assertions of an expert witness. *Cf. Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997). Accordingly, we accord little weight to Dr. McMurry’s testimony that undue experimentation was required to practice Jackson’s claimed invention.

Jackson's claimed process proceeds by a reaction process that is well known in the prior art,⁵ i.e., the McMurry reaction, and Stampa has stated that the level of the skill in the art is high. (Paper No. 27 at 10). We agree with Stampa that the number of examples in Jackson's specification is low compared to the breadth of Jackson's claims, but the McMurry reaction and the reactants, aliphatic ketones and dibenzosuberones were well-known in the art. Further, Stampa fails to demonstrate that the experimentation required to practice the full scope of the claimed invention is anything other than routine experimentation or that the level of predictability for McMurry carbonyl coupling reactions is low. As noted above, the test for undue experimentation is not merely a measure of whether routine experimentation is required but a question of whether the experimentation required is unduly extensive. *PPG Indus., Inc.* 75 F.3d at 1564, 37 USPQ2d at 1623. Based upon the record identified, we hold that Stampa has failed to meet its burden of proving by a preponderance of the evidence that one skilled in the art could not make and use the full scope of Jackson's claimed invention.

⁵See, e.g., finding of fact ¶ 31 in the Decision on Preliminary Motions (Paper No. 69) reads as follows:

Dr. McMurry testifies that he has authored about 26 papers discussing the use of low-valent titanium carbonyl coupling reactions. His review article entitled, "Carbonyl-Coupling Reactions Using Low-Valent Titanium" was published in *Chemistry Review*, Vol. 89, No. 7 in 1989. (SX 2011 [Second Declaration of Dr. McMurry], ¶ 2).

iii. Written Description

Stampa argues that the term 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene encompasses a genus of thousands of potential compounds and that Jackson's specification exemplifies, at best, only two 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes. (Paper No. 28, p. 7). From this, Stampa concludes that Jackson's claimed process lacks written description.

Stampa cites two Federal Circuit cases to outline the requirements for written description as follows:

To this end, the specification must convey with clarity to one skilled in the art that the patentee had possession of the invention. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). The Federal Circuit has noted that an adequate written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 U.S.Q.P.2d 1601, 1606 (Fed. Cir. 1983). A mere wish or plan is insufficient. See *id.* at 1169-71, 25 U.S.P.Q.2d at 1605-06.

(Paper No. 28, p. 6).

Stampa's arguments regarding written description for the claimed process of preparing 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes are surprising, especially in light of the case law cited by Stampa. Jackson's specification explicitly states that the invention is directed "to a process for the preparation of 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-enes, such as loratadine." (JX 1001, A000106; Jackson '827, col. 1, lines 6-8). Jackson's specification provides *ipsis verbis* support for the genus of 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-enes, a precisely defined genus of compounds.

Stampa Preliminary Motion 3 provides no discernible explanation as to why the *ipsis verbis* language contained in Jackson's specification is insufficient to demonstrate possession of

the claimed process of making 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes. Dr. McMurry's testimony likewise provides no clear explanation as to why the *ipsis verbis* language in Jackson's specification fails to demonstrate possession of the claimed process. Dr. McMurry's testimony parallels Stampa's arguments as it provides conclusory statements that Jackson's claims lack written description. According to Dr. McMurry, Jackson's claimed process is directed to making the "universe" of 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes but Jackson's specification provides only two examples contained in Jackson's specification. (SX 2001, ¶¶ 5-9). From this, Dr. McMurry concludes that Jackson's claims lack written description.

Stampa, as moving party, bears the burden of proving that it is entitled to the relief requested. 37 C.F.R. §1.637(a)^{6,7}. To meet this burden, Stampa must provide fair notice to Jackson and the Board as to its theory as to why one skilled in the art would conclude that Jackson did not possess Jackson's claimed process of making 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes where Jackson's specification provides *ipsis verbis* support for the claimed reaction of known classes compounds (aliphatic ketones and dibenzosuberones),

⁶A new set of rules for contested cases and interferences for the Board was placed into effect on September 13, 2004. 69 Fed. Reg. 49960 (12 August 2004), 1286 Official Gaz.1286 (USPTO September 7, 2004). When a rule is changed during the pendency of a patent application, the rule in effect on the date of the patent issues is the one that should be applied to the patent. *Shockley v. Arcan, Inc.*, 248 F.3d 1349, 58 USPQ2d 1692, 1697 (Fed. Cir. 2001). Our decision on motions however, remains the same whether we apply the "old" rules or the "new" rules. As the parties motions requested relief under the old rules, we have addressed their concerns with respect to the old rules and provided footnotes, where appropriate, to the corresponding new rule. See *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 n.2, 56 USPQ2d 1001, 1005 n.2 (Fed. Cir. 2000) (applying the old rule to a patent issued under the old rule, but noting that the result would be the same under the new rule).

⁷See new rule 37 C.F.R. § 41.208(b), which places burden upon moving party.

which are reacted via a known reaction process (McMurry reaction). In short, Jackson's specification explicitly discloses the claimed generic invention. Based upon the arguments and evidence presented, Stampa has failed to meet its burden of demonstrating that one skilled in the art would fail to understand that Jackson's specification described the claimed invention.

b. Dibenzosuberone or an Aza Derivative Thereof

i. Indefiniteness

Stampa argues that the terminology "dibenzosuberone or an aza derivative thereof" is unclear and indefinite. (Paper No. 26, pages 8-9). According to Stampa, the terminology is unclear as:

... Jackson's claims not only purport to encompass the preparation of a vastly indeterminate number of 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes, but the claims purport to do so using the universe of potential dibenzosuberones or aza derivatives thereof.

(*Id.* at 8). Stampa further contends that Jackson's specification does not remedy the indefiniteness of the claims as it fails to teach a skilled artisan:

... (1) that all dibenzosuberones or aza derivatives thereof behave the same way; (2) that even under the best of conditions, the McMurry Reaction is temperamental (McMurry Declaration, Exhibit 2001, at ¶7); or (3) how one must adjust the reaction for each of the different compounds.

(*Id.* at 8-9).

Dr. McMurry testifies that Jackson's claims broadly recite the use of dibenzosuberones or aza derivatives thereof but fail to teach which of the many dibenzosuberones or aza derivatives thereof would be capable of producing the desired product. (SX 2001, ¶8). Dr. McMurry's

testimony does not state that one skilled in the art could not determine whether or not a particular compound was a “dibenzosuberones or aza derivatives thereof.” Also, Dr. McMurry does not testify that one skilled in the art would be unable to conduct the McMurry reaction with a particular “dibenzosuberones or aza derivatives thereof” and aliphatic ketone and determine if the desired product was formed.

A claim that recites a genus covering thousands of potential compounds is not *per se* indefinite. *In re Gardner*, supra. Further, Stampa has failed to identify sufficient and credible evidence of record that the use of the terminology “dibenzosuberones or aza derivatives thereof” does not reasonably apprise those skilled in the art of the scope of the invention.

ii. Enablement

Stampa alleges that one skilled in the art could not make and use the claimed process as the claims are directed to a process of preparing any 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-ene with any “dibenzosuberones or aza derivatives thereof.” (Paper No. 27, pages 10-11). Similar to the argument made with respect to indefiniteness, Stampa states that Jackson’s specification fails to teach a skilled artisan:

... (1) that all dibenzosuberones or aza derivatives thereof behave the same way; (2) that even under the best of conditions, the McMurry Reaction is temperamental (McMurry Declaration, Exhibit 2001, at ¶7); or (3) how one must adjust the reaction for each of the different compounds.

(*Id* at 11). Stampa, applying the Wands factors, concludes that Jackson fails to sufficiently teach how to make and use the claimed invention and that the amount of experimentation required to practice the invention is undue. (*Id* at 11-12).

Dr. McMurry's testimony regarding the lack of enablement regarding the terminology "dibenzosuberones or aza derivatives thereof" is generally directed to his concern that "a skilled artisan would not know which of the many dibenzosuberones or aza derivatives thereof would be capable of producing any 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-ene." (SX 2001, ¶ 8). Additionally, as mentioned above, Dr. McMurry testified that the McMurry reaction is somewhat temperamental and requires that one skilled in the art exercise care and precision. (SX 2001, ¶ 7).

Dr. McMurry's testimony does not demonstrate that undue experimentation is required to determine which "dibenzosuberones or aza derivatives thereof" are capable of forming a desired 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-ene using a known carbonyl coupling reaction, i.e., the McMurry reaction. Dr. McMurry fails to establish that one of ordinary skill in the art could not predict with reasonable certainty whether or not a particular dibenzosuberone or aza derivative thereof would be capable of reacting with a given aliphatic ketone to form a desired 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-ene. Dr. McMurry's testimony that care and precision must be used with a McMurry reaction does not demonstrate that the reaction is difficult to conduct or that the alleged experimentation necessary to practice the full scope of Jackson's claims is anything other than routine. As noted above, the test for undue experimentation is not merely a measure of whether routine experimentation is required but a question of whether the experimentation required is unduly extensive. *PPG Indus., Inc.* 75 F.3d at 1564, 37 USPQ2d at 1623. Additionally, Dr. McMurry's testimony does not explicitly address the implications of Jackson's specific teaching that preferably the "dibenzosuberone or

aza derivatives thereof' is of a particular formula I that is defined in Jackson's specification. ('827 specification, JX 1001, A000106, col. 2, lines 26-43). We, therefore, conclude that Dr. McMurry's testimony fails to provide a sufficient basis for his conclusion that one skilled in the art could not practice the full scope of Jackson's claims due to the many possible dibenzosuberones or aza derivatives thereof.

Stampa, as moving party, bears the burden of proving that one skilled in the art could not make and use the invention claimed by Jackson. Stampa's allegation that undue experimentation is required to practice Jackson's claimed invention is not supported by credible evidence of record. Stampa, on the record provided, fails to demonstrate that a balancing of the *Wands* factors lead to a conclusion that the amount of experimentation is excessive given the nature and predictability of the art combined with the "high" level of skill in the art. Based upon our analysis of Jackson's claims in light of Stampa's allegations and supporting evidence, we conclude that Stampa fails to demonstrate that one skilled in the art, conducting routine experimentation would, when exercising routine care, have had difficulty reacting the reactants recited in Jackson's process claims, including the disputed "dibenzosuberones or aza derivatives thereof," via the art recognized carbonyl coupling McMurry reaction and arriving at a desired 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-ene.

iii. Written Description

Stampa argues that Jackson's specification only exemplifies two preferable aza derivatives and that this is insufficient written description for the claimed universe of potential

“dibenzosuberones or aza derivatives thereof” recited in Jackson’s involved claims. (Paper No. 28, pages 7-8). Stampa further states that written description is lacking as Jackson’s specification fails to teach a skilled artisan:

... (1) that all dibenzosuberones or aza derivatives thereof behave the same way; (2) that even under the best of conditions, the McMurry Reaction is temperamental (McMurry Declaration, Exhibit 2001, at ¶7); or (3) how one must adjust the reaction for each of the different compounds.

(*Id* at 8). McMurry’s declaration testimony is cited as supporting Stampa’s allegations and states that the McMurry reaction is somewhat temperamental and that care and precision is required and further notes that one skilled in the art would not know in advance which “dibenzosuberone or aza derivatives thereof” are capable of producing the desired 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes. (SX 2001, ¶¶ 7-8).

Stampa Preliminary Motion 3 and Dr. McMurry’s declaration do not sufficiently explain why the terminology “dibenzosuberone or aza derivatives thereof” fails to provide a precise definition of the intended class of reactants required by Jackson’s claims. Further, neither Stampa nor Dr. McMurry provides a sufficient explanation of why the *ipsis verbis* language in Jackson’s specification fails to provide an adequate basis to conclude that the inventors possessed the claimed subject matter where known classes of reactants are reacted via a known reaction process to form a desired genus of compounds particularly given the explicit disclosure of a “dibenzosuberone or aza derivative thereof” defined by formula I in Jackson’s specification. On the record identified, we conclude that Stampa has failed to meet its burden of proving that Jackson’s claims lack written description due to their use of the “dibenzosuberone or aza derivatives thereof” terminology.

c. Aliphatic Ketone and Cyclic Aliphatic Ketone

i. Indefiniteness

Stampa states that aliphatic ketones can be either cyclic or acyclic and that “[t]here are an incredibly vast number of cyclic and acyclic aliphatic ketones.” (Paper No. 26, p. 9). According to Stampa, Jackson’s specification does not give an example of any acyclic aliphatic ketones and that there is no support for the thousands of possible acyclic aliphatic ketones. (*Id.*). Stampa concludes that because there are so many aliphatic ketones to choose from, “the skilled artisan would not know which species would work in the Jackson claims absent excessive experimentation.” (*Id.* at 10-11).

Dr. McMurry’s declaration testimony identifies aliphatic ketones, and a subgenus of cyclic aliphatic ketones, as “grossly overbroad” classes of compounds as there is an indefinite number of species that could fall within them. (SX 2001, ¶ 11). Dr. McMurry also testifies that “extreme undue experimentation” would be necessary to practice the invention as there is such a great number of aliphatic ketones from which to choose. (*Id.*).

As discussed above, a claim is not indefinite merely because it is broadly written. *In re Gardner, supra*. Rather, a claim is indefinite if the scope of the invention cannot be determined with a reasonable degree of certainty. Stampa does not allege, nor does Dr. McMurry testify, that one skilled in the art could not determine whether or not a particular compound was an aliphatic ketone. Further, neither Stampa nor Dr. McMurry provides a credible basis to conclude that one skilled in the art would be unable to conduct the claimed reaction process to determine whether or not a particular aliphatic ketone was capable of forming the desired 5,6-dihydro-11H-

dibenzo[a,d] cyclohept-11-enes. Stampa does not explain sufficiently or provide credible evidence demonstrating that one skilled in the art is unable to determine the scope of Jackson's invention due to the term "aliphatic ketones."

Additionally, Stampa Preliminary Motion 3 provides a one sentence statement directing our attention to a footnote in an article that suggests that Jackson's ethyl-4-oxopiperidine-1-carboxylate is a heterocyclic ketone and not an aliphatic ketone. Given Stampa's cursory treatment of the commentator's article, we are not certain whether or not Stampa has adopted the commentators's position stated in the article.

Regarding the footnote, Jackson's specification explicitly states that Jackson's "aliphatic ketone is cyclic and particularly preferably an optionally N-substituted piperidone compound." (JX 1001, col. 2, lines 48-51). Further, Stampa's expert, Dr. McMurry testifies that aliphatic ketones can be cyclic or acyclic (SX 1001, ¶ (9) and at least one organic chemistry text defines aliphatic as encompassing cycloalkanes, cycloalkenes or any of their derivatives and distinguishes aliphatic compounds from aromatic compounds. (Solomon, Organic Chemistry, p. 468). Thus, it appears that a piperidone, including an optionally N-substituted piperidone may reasonably be considered a cyclic aliphatic, i.e., non-aromatic ketone.

Jackson's definition of aliphatic ketone as encompassing an optionally N-substituted piperidone compound is clearly stated in Jackson's specification. Even assuming that Jackson's definition of the optionally N-substituted piperidone compound is contrary to the conventional meaning, something that Stampa has not demonstrated on this record, a patentee can act as his or her own lexicographer to specifically define terms of a claim contrary to their ordinary meaning,

as long as the patentee deliberately and clearly point out how the term differs from the conventional understanding. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249, 48 USPQ2d 1117, 1121 (Fed. Cir. 1998). On this record, Stampa fails to meet its burden of proving that the optionally N-substituted piperidone compound is indefinite as it appears in Jackson's claims.

ii. Enablement

Stampa argues that an aliphatic ketone, as recited in Jackson's involved claims, encompasses both cyclic and acyclic ketone and that there is an incredibly vast number of such ketones. (Paper No. 27, p. 12). Stampa states that Jackson's specification does not provide guidance as to which aliphatic ketones can be used in Jackson's claimed process and that Jackson does not provide any examples of acyclic ketones. (*Id.*). Stampa recognizes that Jackson's specification identifies certain aliphatic ketones as preferred, but Stampa takes the position that even Jackson's preferred class of aliphatic is "incredibly overbroad." (*Id.* at 12-13). Stampa concludes that, based upon Stampa's interpretation of the facts, Jackson's claims fail to satisfy the enablement requirements when analyzed in light of the *Wands* factors. (*Id.* at 14).

Dr. McMurry's testimony (SX 2001) is relied upon by Stampa to demonstrate Jackson's alleged lack of enablement. Dr. McMurry testifies that there are a vast number of cyclic and acyclic ketones and that Jackson's specification does not provide guidance as to which specific acyclic or cyclic ketones can be used to prepare a desired 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene. (SX 2001, ¶ 9). Dr. McMurry also testifies that Jackson's preferred class of

cyclic aliphatic ketones is “grossly overbroad” and includes an “indefinite number of species.” (*Id.* at ¶ 11). Dr. McMurry states that it would require undue experimentation for one skilled in the art to practice Jackson’s claimed processes given the number of aliphatic ketones to choose from. (*Id.* at ¶ 11).

Dr. McMurry’s testimony appears to recognize that the genus of aliphatic ketones, albeit broad, represents a defined and generally understood class of compounds. (See, e.g., *id.* at ¶ 9). Dr. McMurry does not testify that one skilled in the art could not understand the nature of Jackson’s claims or that one could not predict with reasonable certainty whether or not a particular aliphatic ketone is capable of reacting with a particular dibenzosuberone to form a desired 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-ene. Further, Dr. McMurry identifies the McMurry reaction as somewhat temperamental but states that this requires a skilled artisan to exercise care and precision in conducting the reaction. We find that Dr. McMurry fails to provide a sufficient basis to support his conclusion that the Jackson’s claimed process of reacting aliphatic ketones with a dibenzosuberone or an aza derivative thereof in the presence of a zinc generated low valent titanium requires undue experimentation or even excessive experimentation in order to practice the full scope of Jackson’s claims.

Stampa’s allegation that undue or excessive experimentation is required to practice Jackson’s claimed invention is not supported by credible evidence of record. Stampa, on the record provided, fails to demonstrate that a balancing of the *Wands* factors lead to a conclusion that the amount of experimentation is excessive given the nature and predictability of the art combined with the “high” level of skill in the art. In particular, we conclude that Stampa fails to

demonstrate that one skilled in the art conducting routine experimentation would have difficulty practicing the full scope of Jackson's claimed process where known classes of compounds are reacted via a known reaction to produce a desired 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-ene.

Stampa bears the burden of proving that it is entitled to the relief it requests. 37 C.F.R. §1.637(a)⁸. Stampa's request that Jackson's claims be held unpatentable for lack of enablement stemming from the use of the term "aliphatic ketones" is denied as Stampa has failed to meet its burden of proof.

iii. Written Description

Stampa argues that Jackson's claimed aliphatic ketone and cyclic aliphatic ketone lack written description. (Paper No. 28, p. 8). Stampa states that aliphatic ketones can be cyclic or acyclic. According to Stampa, Jackson claim 1 requires the use of aliphatic ketones and Jackson claim 6 limits the aliphatic ketones of claim 1 to cyclic ketones, thus implying that the aliphatic ketones of Jackson claim 1 encompass acyclic ketones. Stampa argues that Jackson's specification does not exemplify or provide specific blazemarks for acyclic ketones. (*Id.* at 8-11).

Stampa Preliminary Motion 3 relies upon Dr. McMurry's testimony to support its contention that Jackson's claimed aliphatic ketones and cyclic aliphatic ketones lack written description. Dr. McMurry's testimony appears to acknowledge that aliphatic ketones are a

⁸See new rule 37 C.F.R. § 41.208(b), which places burden upon moving party.

known class of compounds. (SX 2001, ¶ 7, “. . . which aliphatic ketone from the hundreds available to a skilled artisan . . .”). Dr. McMurry recognizes that aliphatic ketones can be broken down into at least two classes: cyclic and acyclic. (*Id.* at ¶ 9). Dr. McMurry testifies that there is no written description in Jackson’s specification of which of the “great number of species” of cyclic aliphatic ketones or which of the “vastly indeterminate and indefinite” number of aliphatic ketones could be used to make the desired 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-enes. (*Id.* at ¶ 11).

Stampa Preliminary Motion 3 and Dr. McMurry’s declaration do not sufficiently explain why the terminology “aliphatic ketone” fails to provide a precise definition of the intended class of reactants required by Jackson’s claims. Further, neither Stampa nor Dr. McMurry provides a sufficient explanation of why the *ipsis verbis* language in Jackson’s specification that refers to “aliphatic ketones” fails to provide an adequate basis to conclude that the inventors possessed the claimed subject matter where known classes of reactants, such as “aliphatic ketones” are reacted via a known reaction process to form a desired genus of compounds.

Citing *In re Ruschig*⁹ and *In re Arkley*,¹⁰ Stampa states that case law provides that the selection of a single, undisclosed species is akin to the identification of a single tree in a large forest and requires appropriate blazemarks. (Paper No. 28, p. 13). Stampa is of the opinion that the blazemark rationale is “obviously appropriate here.” (*Id.*).

⁹379 F.2d 990, 154 USPQ 118 (CCPA 1967).

¹⁰455 F.2d 586, 172 USPQ 524 (CCPA 1972)

Stampa's contention that the acyclic ketones in Jackson's claims lack sufficient blazemarks is difficult to understand. Jackson's specification describes aliphatic ketones and describes cyclic ketones as preferred. Dr. McMurry recognizes that aliphatic ketones can be cyclic or acyclic. Using Stampa's rationale, by identifying a preference for cyclic ketones, Jackson has created blazemarks to a specific and identifiable portion of the aliphatic genus. We fail to understand how Jackson's preference for one portion of the aliphatic genus, cyclic, over another, acyclic, is comparable to describing a large genus and later claiming a specific individual specifies.

The term aliphatic ketone, as defined by Jackson's specification, has a specific meaning. Jackson's specification provides *ipsis verbis* support for Jackson's claims whereby aliphatic ketones are reacted with dibenzosuberones or aza derivatives thereof to form a desired product. The fact that Jackson's specification identifies a preference for one class of aliphatic ketones over another class that is not explicitly mentioned does not *per se* deprive the term aliphatic ketone of written description. Stampa's contention that this preference for the identified cyclic aliphatic ketones and Jackson's alleged failure to explicitly discuss acyclic aliphatic ketones fails to support a conclusion that all of Jackson's claims are thereby rendered invalid by Jackson's use of the term aliphatic ketone. On the record identified, we conclude that Stampa has failed to meet its burden of proving that Jackson's claims lack written description due to the use of the "aliphatic ketone" and "cyclic aliphatic ketone" terminology.

d. Intermediate Diol of Formula III

i. Indefiniteness

Stampa notes that Jackson claim 12 further limits the process of claim 1 by requiring the formation of an intermediate diol of a specific formula III. (Paper No. 26, p. 11). Stampa states that Jackson's intermediate diol is indefinite as Jackson's specification does not teach a skilled artisan that all of the possible permutations of the formula III intermediate diol behave the same way and that the McMurry reaction is temperamental. (*Id.*).

Stampa Preliminary Motion 1 directs our attention to ¶ 7 of Dr. McMurry's first declaration (SX 2001) as supporting its position that Jackson's intermediate diol is indefinite. With respect to Jackson's intermediate diols, ¶ 7 of Dr. McMurry's first declaration merely states that a skilled artisan reading Jackson's claims would be hard pressed to know which intermediate diol species of formula III could be produced and that the McMurry reaction is temperamental such that a skilled artisan need exercise care and precision when conducting the reaction. (SX 2001, ¶ 7).

Dr. McMurry fails to provide a sufficient basis for his conclusion that one skilled in the art would be hard pressed to know in advance which intermediate diols could be produced during a McMurry reaction, i.e., a carbonyl coupling reaction. Dr. McMurry does not testify that one skilled in the art would fail to understand whether a particular compound fell within the scope of Jackson's defined intermediate diols of formula III. Dr. McMurry does not specifically testify that the formation of the intermediate diols was unpredictable or that the determination of

whether a particular intermediate diol could be formed involved more than routine experimentation.

Stampa has failed to identify sufficient and credible evidence that Jackson's use of the intermediate diol terminology with reference to a specifically identified formula III does not reasonably apprise those skilled in the art of the scope of the invention.

ii. Enablement

Stampa alleges that Jackson's claimed intermediate diol of formula III lacks enablement. Stampa bases this conclusion on the alleged fact that Jackson's specification fails to teach a skilled artisan that all of the intermediate diols of formula III behave the same way and that the McMurry reaction is temperamental. (Paper No. 27, pages 14-15). As with its indefiniteness motion, Stampa relies upon ¶ 7 of Dr. McMurry's first declaration to support its conclusion. (*Id.*). Stampa applies the Wands factors, but does not cite any supporting evidence for its conclusions that: 1) the nature of the claims is unclear; 2) the amount of direction provided by Jackson is lacking; and 3) Jackson's loratadine example is insufficient to enable the claims. (*Id.* at 15).

Stampa has failed to meet its burden of establishing that one skilled in the art required undue experimentation to make and use the intermediate diols of formula III. Stampa has failed to demonstrate with credible evidence that the level of predictability of an art recognized carbonyl coupling reaction, i.e., a McMurry reaction, is low and that one skilled in the art would have required more than routine experimentation to practice the full scope of the claimed

intermediate diols of formula III. Specifically, Stampa directs our attention to Dr. McMurry's first declaration, but this declaration does not appear to mention or provide a credible basis for concluding that Jackson's claimed intermediate diols were unpredictable, unexpected or required undue experimentation to obtain.

iii. Written Description

Stampa's arguments concerning the alleged lack of written description for Jackson's intermediate diol of formula III appear identical to Stampa's indefiniteness arguments but with the term "written description" replacing the terms "indefinite" and "unclear and indefinite." (Compare Paper No. 26, pages 11-12 and Paper No. 28, pages 13-14).

As argued by Stampa, written description "requires a precise definition, such as by structure, formula, chemical name, or physical properties." (Paper No. 28, p. 6, citing *Fiers v. Revel*, *supra*). Stampa's arguments fail to explain why Jackson's intermediate diols, which are defined as being of a specific formula III and are *ipsis verbis* described in Jackson's specification, fail to fulfill the written description requirement. Dr. McMurry's cited testimony does not identify why one skilled in the art would fail to understand the nature of Jackson's intermediate diols of the specifically identified formula III. Further, Dr. McMurry's testimony does not provide a credible basis to conclude that Jackson's specification fails to reasonably convey to those skilled in the art that Jackson possessed the claimed process wherein the intermediate diol of Jackson claim 12 is prepared.

Stampa bears the burden of establishing that Jackson's process wherein the intermediate diol of formula III is prepared lacks written description. Stampa fails to meet this burden.

e. X denotes Nitrogen or CH

i. Indefiniteness

Stampa states that claim 2 of Jackson's '827 patent and '894 application limit the respectively recited dibenzosuberone or aza derivative thereof to a specific formula I wherein X is either N or CH. (Paper No. 26, p. 12). Stampa contends that Jackson's specification does not support the recitation of X being CH and does not support the universe of aza derivatives, i.e., X being N. According to Stampa, Jackson's specification fails to apprise the skilled artisan of what Jackson intends to claim. (*Id.*).

Stampa relies upon ¶ 8 of Dr. McMurry's first declaration to support its position. Regarding the X being N or CH, Dr. McMurry testifies that the claims broadly recite X to be N or CH and also states that the specification provides no guidance that would lead a skilled artisan to practice the claimed invention. (SX 2001, ¶ 8).

Jackson '827 and '894 claim 2 is as follows:

A process as claimed in claim 1 wherein said dibenzosuberone or aza derivative thereof is of formula I: [formula omitted] wherein: X denotes nitrogen or CH; and R¹, R², R³ and R⁴ which may be the same or different independently denote hydrogen or a halogen.

(JX 1001, claim 2).

As apparent from the plain language of Jackson '827 and '894 claim 2, the recited dibenzosuberones and aza derivatives thereof are expressly limited to a specific set of

compounds. Stampa's arguments and alleged evidence in support thereof fail to explain why one skilled in the art could not understand the scope of the specifically identified structure of formula I recited in Jackson claim 2. Given the narrowly defined formula (I) with the limited number of moieties permissible we have difficulty fathoming how Jackson's claim terminology "X denotes nitrogen or CH" is indefinite. On its face, Stampa's indefiniteness argument appears frivolous.

Regarding indefiniteness, Stampa specifically argues that Jackson's specification does not "adequately support" the recitation that X is CH or N. (Paper No. 26, p. 12). Stampa appears to mistake written description "support" for lack of definiteness. To the extent "support" is required for definiteness, we note that Jackson's specification unmistakably contains this recitation.¹¹ Stampa's request that Jackson's claims be held unpatentable due to Jackson's claim recitation "X denotes nitrogen or CH" is denied.

ii. Enablement

Stampa argues that:

The specification does not adequately support the recitation of X being CH and does not support the universe of aza [nitrogen] derivatives thereof. Thus, undue experimentation would be required for a skilled artisan to practice the claimed invention.

(Paper No. 27, p. 15). As mentioned above, Stampa's allegation that Jackson's specification does not support the recitation X being CH or N is not well understood.

¹¹We note that Jackson's '827 patent is only 8 columns long and the structure of formula I is provided on column 2 with the structure alone taking up 10 lines of the column. Directly below the structure of formula I, Jackson's specification states "wherein: X denotes nitrogen or CH."

Stampa relies upon the first declaration of McMurry to support its contention that undue experimentation would be required for the recitation that X is CH or N. Yet, Dr. McMurry's testimony regarding X being CH or N in Jackson formula I is cursory and fails to explain why one skilled in the art could not practice this embodiment. For example, Dr. McMurry does not testify that one skilled in the art could not predict with reasonable certainty whether the specifically identified compounds of Jackson formula I would undergo an art recognized McMurry reaction with an aliphatic ketone to form a desired product. Nothing in our rules or in our jurisprudence requires us to credit the unsupported assertions of an expert witness. *Cf. Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997). We accord little, if any, weight to Dr. McMurry's general conclusion that the specification provides no guidance as to how to practice the invention without excessive and burdensome experimentation. Stampa fails to meet its burden of proof that it is entitled to the relief it requests. 37 C.F.R. §1.637(a)¹². Stampa's request that Jackson's claims be held unpatentable for lack of enablement arising from Jackson's claim 2 recitation that X is N or CH is denied.

iii. Written Description

Stampa's argues that:

The specification does not adequately support the recitation of X being CH and does not support the universe of aza [nitrogen] derivatives. Thus, both the skilled artisan and the public in general are disadvantaged. When read in light of the specification, a skilled artisan would not know whether Jackson had possession of

¹²See new rule 37 C.F.R. § 41.208(b), which places burden upon moving party.

a process utilizing every dibenzosuberone or every aza derivative thereof as claimed.

(Paper No. 28, pages 14-15).

Jackson claim 2 limits the dibenzosuberones or aza derivatives thereof of Jackson claim 1 to a specifically identified set of compounds having the structure of formula I wherein X is N or CH and R₁-R₄ are independently H or halogen. The structure of formula I and the explanation of the X and R₁-R₄ moieties is clearly set forth in Jackson's specification. Stampa does not explain why the *ipsis verbis* support in Jackson's specification fails to adequately describe this aspect of the claimed invention of Jackson claim 2. Further, while Stampa argues that the artisan and public are disadvantaged by the alleged lack of support in Jackson's specification, Stampa appears to ignore Jackson's *ipsis verbis* support.

Stampa argument is frivolous on its face and it appears that in making this allegation Stampa did not read claim 2 carefully. Stampa request that Jackson's claims be held unpatentable due to a lack of written description Jackson's recitation that X is CH or N in Jackson claim 2 is denied.

f. Jackson's Alleged Exclusion of a Tertiary Amine from its Claims

Stampa Preliminary Motions 1, 2 and 3 allege that Jackson's claims are indefinite, lack enablement and lack written description as Jackson has previously argued that its claims exclude a tertiary amine but no such guidance is provided by Jackson specification. (Paper No. 26, pages 14-15; Paper No. 27, pages 16-17; and Paper No. 28, pages 15-16). During the course of this interference Jackson's involved process claims have been construed as encompassing the use of a

tertiary amine. (Notice Declaring Interference, Paper No. 1 and Decision on Preliminary Motions, Paper No. 69 at 32-36). Accordingly, for the reasons of record, Stampa's request is *denied*.

B. Decision on Stampa's Request for Reconsideration

The Decision on Preliminary Motions denied Stampa Preliminary Motions 1, 2 and 3 as to Jackson '827 patent claims 3-5, 7-11 and 13-17, and '894 application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28. The basis for the denial was that Stampa Preliminary Motions 1, 2, and 3 fail to specifically identify the particular basis or sufficient evidence that would support a finding of unpatentability for these claims.

Stampa's request for reconsideration identifies the three following points that the Board allegedly misapprehends or overlooks:

- i. Stampa Preliminary Motions 1-3 asserted arguments based upon claim terms that affect all of Jackson's '827 and '894 claims by virtue of explicit recitation or dependence.
- ii. The unpatentability of Jackson's claims is not limited to a discreet subset of claims as identified in the Decision.
- iii. A decision that all of Jackson's claims are unpatentable leads to a termination of the interference.

(Paper No. 110, p. 1).

Stampa's request for reconsideration is based upon the premise that Stampa Preliminary Motions 1, 2 and 3 identify specific Jackson claim terminology that renders all of Jackson's claims unpatentable and is not limited to those Jackson claims that are specifically identified in the preliminary motions. Stampa's request for reconsideration provides the following table that

sets forth a summary of the disputed Jackson claim terminology and those Jackson claims that Stampa alleges are unpatentable stemming from the use of the disputed language.

| Complained of Jackson Claim Recitation | Affected Jackson Patent Claim(s) | Affected Jackson Application Claim(s) |
|--|----------------------------------|---------------------------------------|
| 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-ene | 1-16 | 1-16, 18-28 |
| Dibenzosuberone or an Aza Derivative Thereof | 1, 6-17 | 1, 6-28 |
| Aliphatic Ketone | 1-5, 10-17 | 1-5, 10-28 |
| Cyclic Aliphatic Ketone | 6-9 | 6-9 |
| Intermediate Diol | 12 | 12 |
| X denotes Nitrogen or CH | 2-4 | 2-4 |

(Paper No. 110, p. 10). Stampa does not identify where Stampa Preliminary Motions 1, 2 or 3 identified the claim groupings appearing in the above table.

Stampa's request for reconsideration alleges that Stampa Preliminary Motions 1, 2 and 3 provide a basis for concluding that Jackson's dependent claims are unpatentable stemming from the use of terminology appearing in the independent claims. Stampa is reminded that a party filing a motion is responsible for explaining its position with specificity. 37 C.F.R. §1.637(a)¹³. By particularly explaining its position, a moving party provides notice to an opponent and the Board as to the basis for its request. For example, Jackson's claims are, generally directed to, a process of reacting a defined genus of compounds A with a defined genus of compounds B in the presence of zinc generated low valent titanium to form a defined genus of products C. Certain of Jackson's dependent claims provide limitations to this process by further defining the types of

¹³See new rule 37 C.F.R. § 41.208(b), which places burden upon moving party.

reactants A or B. Stampa's Preliminary Motions 1, 2 and 3, by alleging that products C lack clarity, description and enablement, must attempt to explain, with appropriate evidence, why one skilled in the art viewing limitations to reactants A and/or B would not understand the resulting products C to be definite, described and/or enabled.

Stampa's allegations regarding the six disputed claim terms appearing in Jackson's involved claims have been considered. Based upon the record presented, Stampa fails to demonstrate by a preponderance of the evidence that Jackson's claims using the disputed terminology are indefinite, lack enablement and/or written description. Accordingly, Stampa's request for reconsideration has been considered but is denied as to the relief requested.

We make the following observations regarding Stampa's request for reconsideration. A party requesting reconsideration of an interlocutory decision must specify with particularity points believed to have been misapprehended or overlooked in rendering the decision. 37 C.F.R. § 1.640(c).¹⁴ A request for reconsideration is not a new opportunity to raise issues that could have been raised in the motion being reconsidered.

Stampa's Preliminary Motions 1, 2 and 3 did not refer with particularity to Jackson '827 patent claims 3-5, 7-11 and 13-17, and '894 application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28. Stampa's request for reconsideration provides various arguments as to why these particular claims are unpatentable for the reasons set forth in Stampa's preliminary motions. Stampa's request for reconsideration does not direct our attention to where in Stampa Preliminary Motions 1, 2 and 3 Stampa identified and addressed the limitations for this set of

¹⁴See new rule 37 C.F.R. §41.125.

claims. Stampa's failure to identify where these allegations were initially presented raises a concern that these allegations may be new issues that Stampa is attempting to belatedly advanced in a request for reconsideration.

Stampa's request for reconsideration alleges the interference should be terminated because all of Jackson's claims, including the Counts (Jackson '827 and '894 Claims 17) are unpatentable. In particular, Stampa argues that Jackson '827 and '894 claims 17 are unpatentable as the claims do not exclude the use of additional unrecited steps in the claimed process of obtaining loratadine. Stampa fails to provide a citation to the specific page(s) of Stampa's Preliminary Motions 1, 2 or 3 where this argument was advanced. Additionally, we note that Stampa does not cite to specific evidence of record to support its conclusion and fails to explain Dr. McMurry's general testimony that "except as to possibly claim 17" Jackson's involved claims are unpatentable as lacking clarity, description and enablement. (SX 2001, ¶ 5). Stampa's failure to provide a citation to where Stampa Preliminary Motions 1, 2 or 3 set forth Stampa's specific allegations as to the unpatentability of Jackson '827 and '894 claims 17 raises concerns that Stampa's request for reconsideration is an attempt to belatedly rebrief its motions.

IV. ORDER

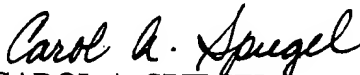
Based upon the evidence of record, it is:


ORDERED that Stampa Preliminary Motion 1 requesting judgment that all of Jackson's involved claims be found unpatentable for lack of definiteness is *denied*.


FURTHER ORDERED that Stampa Preliminary Motion 2 requesting judgment that all of Jackson's claims involved be found unpatentable for lack of enablement is *denied*.

FURTHER ORDERED that Stampa Preliminary Motion 3 requesting judgment that all of Jackson's involved claims be found unpatentable for lack of written description is *denied*.

FURTHER ORDERED that Stampa's Request for Reconsideration has been considered and is *denied*.


CAROL A. SPIEGEL
Administrative Patent Judge


SALLY GARDNER LANE
Administrative Patent Judge


MICHAEL P. TIERNEY
Administrative Patent Judge

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